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NOTIFICATION CONCERNING
TRANSMITTAL OF COPY OF INTERNATIONAL
PRELIMINARY REPORT ON PATENTABILITY
(CHAPTER I OF THE PATENT COOPERATION
TREATY)

(PCT Rule 44bis.1(c))

To:

REC'D OCT 05 2006

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Date of mailing (day/month/year)
28 September 2006 (28.09.2006)

Applicant's or agent's file reference
020.0328.PC.

IMPORTANT NOTICE

International application No.
PCT/US2005/008650

International filing date (day/month/year)
15 March 2005 (15.03.2005)

Priority date (day/month/year)
15 March 2004 (15.03.2004)

Applicant

CARDIAC PACEMAKERS, INC. et al

The International Bureau transmits herewith a copy of the international preliminary report on patentability (Chapter I of the Patent Cooperation Treaty)

The International Bureau of WIPO
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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 020.0328.PC.	FOR FURTHER ACTION		See item 4 below
International application No. PCT/US2005/008650	International filing date (<i>day/month/year</i>) 15 March 2005 (15.03.2005)	Priority date (<i>day/month/year</i>) 15 March 2004 (15.03.2004)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant CARDIAC PACEMAKERS, INC.			

1. This International preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 10 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | |
|---|---|
| <input checked="" type="checkbox"/> Box No. I | Basis of the report |
| <input checked="" type="checkbox"/> Box No. II | Priority |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input checked="" type="checkbox"/> Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability: citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI | Certain documents cited |
| <input type="checkbox"/> Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 25(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report
19 September 2006 (19.09.2006)

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PATENT COOPERATION TREATY

REC'D 15 DEC 2005

WIPO

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From the
INTERNATIONAL SEARCHING AUTHORITY

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To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/008650

International filing date (day/month/year)
15.03.2005

Priority date (day/month/year)
15.03.2004

International Patent Classification (IPC) or both national classification and IPC
G06F1/00, H04L9/00, H04L29/00, A61B5/00, A61N1/00

Applicant
CARDIAC PACEMAKERS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 65.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/008650

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2005/008650

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 11-26, 40-55

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 11-26, 40-55
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☐ See separate sheet for further details

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-10, 27-29, 30-39, 56-59

Box No. V Reasoned statement under Rule 43b/s.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-10, 27-29, 30-39, 56-59
	No: Claims	
Inventive step (IS)	Yes: Claims	1-10, 27-29, 30-39, 56-59
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-10, 27-29, 30-39, 56-59
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV.

The application lacks unity within the meaning of Article 17 (3)(a) PCT for the reasons explained below:

The separate inventions/groups of inventions are:

1-10, 27-29, 30-39, 56-59

using different interfaces for establishing and for transacting secure communication

This group also contains claims that do not include this feature but do not require an extra search

11-16, 40-45

maintaining the key in the medical device

17-20, 46-49

maintaining the key in a secure database

21-26, 50-55

maintaining the key in a token

They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:

The single concept linking together the claims is a system according to claim 1.

The closest prior art is a system for transacting a data exchange session with an implantable medical device. Such a system is common general knowledge. The distinguishing features of claim 1 over said prior art are the means described in claim 1 for securely authenticating the data exchange session.

Starting from the closest prior art, the problem to be solved by the invention is to securely authenticate the data exchange session. Authenticating a data exchange is a general task for the person skilled in the art, thus posing the problem is not inventive. When solving this problem, the person skilled in the art would integrate all features of claim 1 into a system according to the closest prior art without an inventive step:

- a crypto key uniquely associated with an implantable medical device to authenticate data during a data exchange session. (It is common general knowledge to use a uniquely

associated key for each entity that needs to authenticate, or similarly encrypt data)
- an external source (it is obvious that there needs to be an external counterpart for the data exchange with the internal device) to establish a secure connection with a secure key repository to securely maintain the crypto key (it is also obvious that this source needs the key that is needed for authentication and therefore needs to connect to some kind of repository where the key is maintained somehow), and to authenticate authorisation (this is what the system is supposed to do) to access data on the implantable medical device by securely retrieving the crypto key from the secure key repository (obviously the key that is needed for authentication must be retrieved before it can be used).
It is obvious that everything needs to be secure, because this is the purpose of the system. Only if technical features that are employed to reach this goal were included in the claim they could contribute to an inventive step.

Therefore the single general concept is not new and not inventive, contrary to rule 13.1 PCT

The special technical features of the groups of claims over said prior art are:

1. using different interfaces for establishing and for transacting secure communication
this group also contains claims that do not include this feature but do not require an extra search
2. maintaining the key in the medical device
3. maintaining the key in a secure database
4. maintaining the key in a token

It is clear that there is no technical relationship among these technical features, contrary to rule 13.2 PCT

Re Item V.

- 1 Reference is made to the following documents:

D1 : SCHNEIER B: "Applied Cryptography, Second Edition" APPLIED
CRYPTOGRAPHY. PROTOCOLS, ALGORITHMS, AND SOURCE CODE IN C,
NEW YORK, JOHN WILEY & SONS, US, 1996, pages 31-42, XP002236553
ISBN: 0-471-11709-9
D2 : EP 0 756 397 A (HEWLETT-PACKARD COMPANY; AGILENT
TECHNOLOGIES, INC.) 29 January 1997 (1997-01-29)
D3 : US 2002/065099 A1 (BJORNDahl PER ET AL) 30 May 2002 (2002-05-30)
D4 : US 2001/027331 A1 (THOMPSON DAVID L) 4 October 2001 (2001-10-04)
D5 : US 6 434 429 B1 (KRAUS MICHAEL ET AL) 13 August 2002 (2002-08-13)

2 INDEPENDENT CLAIMS

- 2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not inventive in the sense of Article 33(2) PCT for the reasons explained above under Item IV. Document D1 is a standard book documenting the common general knowledge.
- 2.2 The features of independent method claim 30 and independent apparatus claim 59 correspond to the features of system claim 1, therefore the corresponding argumentation applies.

3 DEPENDENT CLAIMS

- 3.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject matter of claim 4 does not involve an inventive step in the sense of Article 33(3)PCT.
- 3.1.1 Document D5, which is considered to represent the most relevant state of the

art to the subject matter of claim 4, discloses (the references in parentheses applying to this document):

- A system for a data exchange session with an implantable medical device (fig. 1), further comprising
- a short range interface logically defining a secured area around the implantable medical device (fig. 7, 47)
- a long range interface logically defining a non-secured area extending beyond the secured area in which to transact the data exchange session (fig. 7, 49)

- 3.1.2 The subject-matter of independent claim 1 differs from the disclosure of D2 in all other features of claim 1 and that :
- a secure connection is established within the secured area
- 3.1.3 The features of claim 1 do not contribute to an inventive step, as explained above.
- 3.1.4 The problem to be solved by the present invention may therefore be regarded as
- how to establish a secure connection
- 3.1.5 When solving this problem, the person skilled in the art would find a solution in D2, which discloses that a secure connection is established ("update a shared security key", abstract) within the secured area ("directly", "when the risk of interception is minimal", abstract).
- 3.1.6 Therefore the features disclosed in claim 1, D2 and D5 would be combined by the skilled person, without exercise of any inventive skills in order to solve the problem posed. The proposed solution in independent claim 1 thus cannot be considered inventive (Article 33(3) PCT).
- 3.2 The other dependent claims do not contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to inventive step, because all additional features are either

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/008650

known from the cited documents or common general knowledge.